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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

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MAY 28 2008

This summary was prepared on April 22nd, 2008.

2. The name of the device is the **Philips OB TraceVue Obstetrical Information Management System SW Revision F.00**. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Obstetrical and Gynecological Monitoring Devices	§884.2740, II	HGM	Perinatal monitoring system and accessories

3. The modified device is substantially equivalent to the previously cleared Philips devices marketed pursuant to **K970456.**

4. The modification is the introduction of Revision F.00 software for the **Philips OB TraceVue Rev.F.00 Obstetrical Information Management System.**

5. The modified device has the same intended use as the legally marketed predicate device. They are intended to acquire and present patient information. They are designed to help the user to monitor and chart the labor of patients in the hospital or clinic. They can alert the user to suspicious traces, but leaves the decision about what action to take to the clinician. All patient related data, such as demographic data, traces, and notes can be stored to optical disk to ensure a complete, permanent record of patient data.

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6. The modified device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance and functionality characteristics of the modified device with respect to the predicate device. Testing involved system level tests, performance tests, and safety testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device. The test results showed substantial equivalence. The results demonstrate that the **Philips OB TraceVue Obstetrical Information Management System SW Rev.F.00** meets all functionality requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Mr. Michael Asmalsky
Quality & Regulatory Affairs
Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard-Str. 2, D-71034 Böblingen
GERMANY

Re: K081203
Trade/Device Name: The Philips OB TraceVue Obstetrical Information Management System Rev.F.00
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: April 23, 2008
Received: April 28, 2008

Dear Mr. Asmalsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081203

Device Name: The Philips OB TraceVue Obstetrical Information Management System Rev.F.00

Indications for Use :

Indications for Use

The Philips OB TraceVue Obstetrical Information Management System is indicated for use in healthcare facilities by healthcare professionals whenever there is a need for comprehensive obstetrical surveillance of patients at central station, all bedsides, nurses' lounges, physicians' lounges and offices.

The Philips OB TraceVue Obstetrical Information Management System allows easy-to-use patient surveillance in hospitals. It is easy to expand and the highly modular implementation offers antepartum and intrapartum alarming and optional storage.
The specific medical indication for use of this device is:

- This device is a prescription device.
- This device is not intended to contact the patient.
- This device is used continuously in Obstetrical / Gynecological departments (OB/GYN).
- Basic and advanced fetal trace alarming for both antepartum and intrapartum applications.
- The physiological purpose is indirect. The device is intended to gather and store patient information and to document relevant monitor information (surveillance) of patients in OB and GYN, as needed by care providers.

Prescription Use (Part 21 CFR 801 Subpart D) yes AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) No

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081203